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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/536,552	03/28/2000	Andrew L. Mason	9926-003-999	5583

20583 7590 04/07/2003

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EXAMINER

EPPS, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/536,552

Applicant(s)

MASON ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4 and 7 is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Response to Amendment***

2. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth below.

Claim 3 recites "[A] composition comprising an isolated Primary Sclerosing Cholangitis, PSC, associated retrovirus comprising a nucleotide sequence comprising SEQ ID NOs. 1, 2, 3, 4, 5, 6, 7, or the compliment thereof."

However, the specification as filed does not provide a sufficient written description to support the full scope of the genus of PSC associated retroviruses that comprise the nucleotide sequences according to SEQ ID NO: 1-7 or compliments thereof.

The specification as filed describes the PSC associated retroviruses according to the present invention as comprising fragments of 20-1000 base pairs or more in length, however the sequences according to SEQ ID NOs: 1-7 of the instant application range from 101 to 126 base pairs in length (see page 11, lines 35-37). Additionally, the specification as filed states that the PSC associated retroviral nucleotide sequences of the present invention include" (a) nucleotide sequences according to SEQ ID NOs: 1, 2, 3, 4, 5, 6, or 7 and fragments thereof encode a portion of the PSC associated retroviral genome of the present invention; (b) nucleotide sequences that

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comprise SEQ ID NO: 1, 2, 3, 4, 5, 6, or 7 that encode a PSC associated retroviral genome or a portion, mutant or allelic variant thereof.”

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, “Written Description” Requirement. These guidelines state: “[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.”

In the instant case Applicants have described the genus of PSC associated retroviruses encompassed by the instant claims as those retroviruses which comprise the nucleotide sequence according to SEQ ID NO: 1-7 or compliments thereof. However, the sequences according to SEQ ID NO: 1-7, which corresponds to only a portion of a retroviral genome and comprises only about 100 base pairs, is not sufficient to describe the full length genome of all the PSC associated retroviruses encompassed by the instant claims. Moreover, it is noted that the instant claims do not require that the PSC associated retrovirus comprise a genome that comprises a sequence

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according to SEQ ID NO: 1-7, therefore claim 1 broadly reads on a retrovirus that comprises an exogenous nucleotide sequence comprising SEQ ID NO: 1-7.

It is apparent that although the sequences according to SEQ ID NO: 1-7 could potentially be useful to isolate other retroviral sequences having a sequence complementary to one of SEQ ID NO: 1-7, further experimentation is required in order to describe every element of the PSC associated retroviruses that are encompassed by the claimed invention. Since further experimentation is required in order to describe the full scope of compounds encompassed by the claimed invention, it is evident that the full scope of the claimed invention was not "ready for patenting" at the time of filing.

Therefore, at the time of filing Applicants were not in possession of the full scope of compositions comprising a PSC associated retrovirus comprising a nucleotide sequence comprising SEQ ID NOs. 1, 2, 3, 4, 5, 6, 7, or the compliment thereof, as recited in instant claim.

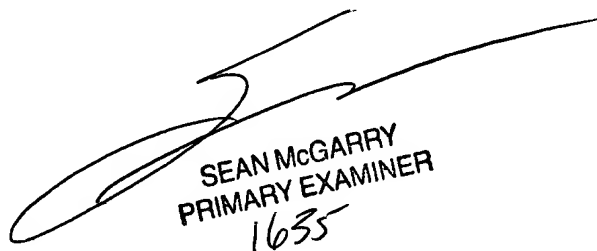
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
April 1, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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